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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/624,981

Applicant(s)

ZDEBLICK ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 61-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 61-104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/22/03 + 6/30/05</u> | 6) <input type="checkbox"/> Other: _____ |

Claim Objections

Claims 62, 77, and 99 are objected to because of the following informalities:

On line 1 of each of these claims, "includes" should be ---further includes--- so that it is clear that additional modifications are being made to the features previously claimed. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 72, 75, 87, 98, and 104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 75, 87, and 98, on line 1 of each claim, "the opening" lacks clear antecedent basis.

Regarding claims 72, 87, and 98 (see, for example, line 7 of claim 72), the language "engages the fusion device" makes it seem as if the fusion device is positively claimed. Since the preamble is clearly limited to only a cap, it is unclear whether the fusion device is positively required. In order to overcome this rejection, the Examiner suggests changing this language to ---adapted to engage the fusion device---.

Regarding claim 104, it depends upon itself so its scope is clearly undeterminable. For this reason, claim 104 will not be evaluated on its merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 66-68, 72, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuslich et al (US 5,458,638). Kuslich anticipates the claim language where the occlusion body as claimed is the cap (147) of Kuslich, the anchor as claimed is the clip (148), and the lip as claimed is the barb ((61) or end of clip (148)); see Figures 10, 12A, 13A, 15, 18-20, and 25 as well as column 8, line 38 et seq. The effective filing date of the present claims is February 11, 1997.

With regard to claim 2 specifically, the flange is the position of the cap (149) that extends past the clips (148).

With regard to claim 66, the curved profile is between the barb and clip.

With regard to claim 68, Applicants are directed to column 7, lines 13-30.

Claims 1, 2, 73, 75, and 77-81 are rejected under 35 U.S.C. 102(e) as being anticipated by Suddaby (US 6,159,244). Suddaby anticipates the claim language where the occlusion body as claimed is plate (40) of Suddaby, the anchor as claimed is arm

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(42,44), and the lip as claimed is hook (46); see Figures 1 to 6 as well as columns 3 and 4.

With regard to claim 2, the flange is defined by groove (not shown) and its outside the groove; see column 3, lines 58-60.

With regard to claim 77, the rim is defined by the groove (not shown).

With regard to claim 81, the arms would inherently have to be resiliently movable in order to function as described where it can extend the body and clip on it to hold it.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 61-65, 74, 76, 87-93, and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suddaby (US 6,159,249) in view of Biedermann et al (US 5,702,461) or Ray et al (WO 91/06261). Suddaby meets the claim language as explained in the Section 102 rejection *supra*, but fails to disclose apertures in the cap as claimed. However, Biedermann (see Figures 3 and 5) or Ray (see Figure 1) teaches that it was known to put apertures in similar devices that are inherently capable of allowing ingrowth and protein ingress due to their macroscopic size. Therefore, it is the Examiner's position that it would have been obvious to put apertures in the plate of Suddaby for the same reasons that Biedermann or Ray does the same and in order to better promote fusion.

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With regard to claim 97 specifically, the configuration or shape of the lip as having a curved profile to match the surface it is to be mated with is "considered to a matter of choice that a person of ordinary skill would have found obvious absent persuasive evidence that the particular configuration . . . was significant"; see MPEP 2144.04 IV B that it incorporated herein by reference thereto.

MPEP 2144.04 IV B. Changes in Shape

In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.)

Claims 70, 84, and 98-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suddaby, Biedermann, and Ray as applied to claims 61-65, 74, 76, 87-93, and 93 above, and further in view of Michelson (US 6,605,089). Suddaby failed to disclose the use of a porous material to make the body or plate as claimed. However, Michelson teaches that it was known to make similar devices in the art of porous materials; see claim 49 thereof. Therefore, it is the Examiner's position that it would have been obvious to make the plate of Suddaby porous for the same reasons that Michelson did the same or in order to promote ingrowth, ongrowth, and spinal fusion as is desired by Suddaby.

Claims 71, 85, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suddaby, Biedermann, Ray and Michelson as applied to claims 70, 84, and 98-103 above, and further in view of Robine (FR 2,710,519). Suddaby fails to disclose the use of a threaded hole for an instrument as claimed. However, Robine

teaches that such was known; see Figures 1 to 4. Therefore, it is the Examiner's position that it would have been obvious to put a threaded instrument hole in the Suddaby plate for the same reasons that Robine does the same and in order to aid in the insertion thereof.

Claims 68, 69, 82, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suddaby (US 6,159,244) in view of Michelson (US 2002/0138144). Suddaby meets the claim language as explained in the Section 102 rejection therewith *supra*, but fails to teach making the plate and arms bioabsorbable. However, Michelson teaches that it was known to make similar caps in similar devices biodegradable or bioabsorbable; see paragraph [0056]. Therefore, it is the Examiner's position that it would have been obvious to make the cap of Suddaby bioabsorbable or biodegradable for the same reasons that Michelson does the same or in order to make the device more open to ingrowth once sufficient ingrowth has occurred to stabilize the bone chips within the device. This additional openness would improve the fusion capabilities of the device.

Claims 94 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suddaby, Biedermann, and Ray as applied to claims 61-65, 74, 76, 87-93, and 93 above, and further in view of Michelson (US 2002/0138144). Suddaby meets the claim language as explained in the Section 102 rejection therewith *supra*, but fails to teach making the plate bioabsorbable. However, Michelson teaches that it was known to make similar caps in similar devices biodegradable or bioabsorbable; see paragraph [0056]. Therefore, it is the Examiner's position that it would have been obvious to make

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the cap of Suddaby bioabsorbable or biodegradable for the same reasons that Michelson does the same or in order to make the device more open to ingrowth once sufficient ingrowth has occurred to stabilize the bone chips within the device. This additional openness would improve the fusion capabilities of the device.

Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suddaby (US 6,159,244) alone. Suddaby meets the claim language except for the curved lip profile as claimed. However, the configuration or shape of the lip as having a curved profile to match the surface it is to be mated with is "considered to a matter of choice that a person of ordinary skill would have found obvious absent persuasive evidence that the particular configuration . . . was significant"; see MPEP 2144.04 IV B that it incorporated herein by reference thereto.

MPEP 2144.04 IV B. Changes in Shape

In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.)

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending

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claims is respectfully requested in response to this Office action unless such applications are stored in image format (i.e. IFW). Generally, those applications filed or amended after July 1, 2003 are image file wrapper (IFW) applications.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Prebilic whose telephone number is (571) 272-4758. The examiner can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
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